

PATENT



## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : Louis J. Theodore et al.  
Filed : February 12, 2002  
For : THREE-STEP PRETARGETING METHODS AND  
COMPOUNDS

Docket No. : 690022.53656C21

Date : February 12, 2002

Commissioner for Patents  
Washington, DC 20231

INFORMATION DISCLOSURE STATEMENT

Commissioner:

In accordance with 37 C.F.R. §§ 1.56 and 1.97 through 1.98, Applicants wish to make known to the Patent and Trademark Office the references set forth on the attached Forms PTO-1449. This application is a continuation and relies, under 35 U.S.C. § 120, on the earlier filing date of prior Application No. 09/316,452, filed May 21, 1999, now allowed; which is a continuation of prior Application No. 08/753,445, filed November 25, 1996; which is a divisional of prior Application No. 08/156,614, filed November 23, 1993, which issued as U.S. Patent 5,578,287; which is a continuation-in-part of prior Application No. PCT/US93/05406, filed June 7, 1993; which is a continuation-in-part of prior Application No. 07/995,383, filed December 23, 1992; which is a continuation-in-part of prior Application No. 07/895,588, June 9, 1992, which issued as U.S. Patent No. 5,283,342.

The references listed on the attached Forms PTO-1449 were submitted to and/or cited by the Patent and Trademark Office in these prior applications and, therefore, are not required to be provided in this application. If the Examiner wishes, copies will be provided upon request. As to any reference supplied, Applicants do not admit that it is "prior art" under 35 U.S.C. §§ 102 or 103, and specifically reserve the right to traverse or antedate any such reference, as by a showing under 37 C.F.R. § 1.131 or other method. Although the aforesaid references are made known to the Patent and Trademark Office in compliance with Applicants' duty to disclose all information they are aware of which is believed relevant to the examination of the above-identified application, applicants believe that their invention is patentable.

Please acknowledge receipt of this Information Disclosure Statement and kindly make the cited references of record in the above-identified application.



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PATENT TRADEMARK OFFICE

Respectfully submitted,

Seed Intellectual Property Law Group PLLC

A handwritten signature in black ink, appearing to read "Richard G. Sharkey", written over a horizontal line.

Richard G. Sharkey, Ph.D.

Registration No. 32,629

RGS:sfl

Enclosures:

Postcard

Forms PTO-1449 (5 Sheets)

ShaneL/256407

FORM PTO-1449 (REV.7-80)	U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	ATTY. DOCKET NO. 690022.53656C21	EXPRESS MAIL NO. EV064839693US
<b>INFORMATION DISCLOSURE STATEMENT</b> <i>(Use several sheets if necessary)</i>		APPLICANTS Louis J. Theodore et al.	
		FILING DATE February 12, 2002	GROUP ART UNIT <i>1641</i> Not yet assigned

10/07/03  
10/07/03  
02/12/02

## U.S. PATENT DOCUMENTS

*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	AA	4,639,365	01/27/87	Sherry	424	9.363	
	AB	4,647,447	03/03/87	Gries et al.	424	9.36	
	AC	4,678,667	07/07/87	Meares et al.	424	1.53	
<i>mac</i>	AD	4,863,713	09/05/89	Goodwin et al.	424	1.57	
	AE	4,923,985	05/08/90	Gansow et al.	540	474	
	AF	5,141,966	08/25/92	Porath	521	32	
	AG	5,246,692	09/21/93	Gansow et al.	424	1.53	
	AH	5,256,395	10/26/93	Barbet et al.	424	1.57	
	AI	5,326,778	07/05/94	Rosebrough	514	387	
	AJ	5,578,287	11/26/96	Theodore et al.	424	1.49	

## FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	TRANSLATION	
					YES	NO
	AK	EP 327 365 ✓	08/09/89	EPO		
	AL	EP 451 824	10/16/91	EPO		
	AM	EP 496 074 ✓	07/29/92	EPO		
	AN	WO 92/12730	08/06/92	WIPO		

OTHER PRIOR ART *(Including Author, Title, Date, Pertinent Pages, Etc.)*

	AO	Axworthy et al., "Antibody pretargeting for radioimmunotherapy: a three-step approach in tumored nude mice," <i>J. Nucl. Med. Proceedings of the 39<sup>th</sup> Annual Meeting</i> 33:880, Abstract No. 234, 1992.
	AP	✓ Bloom, "The Power of Negative Thinking," <i>J. Clin. Invest.</i> 91:1265-1266, April 1993.
	AQ	Catterjee et al., "Idiotypic antibody immunotherapy of cancer," <i>Cancer Immunol. Immunother.</i> 38(2):75-82, February 1994.

EXAMINER

DATE CONSIDERED

\* EXAMINER: Initial if reference considered, whether or not criteria is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant(s).

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	BA	5,608,060	03/04/97	Axworthy et al.	540	474	
	BB	5,630,996	05/20/97	Reno et al.	424	1.49	
	BC	6,022,966	02/08/00	Gustavson et al	540	474	
<b>FOREIGN PATENT DOCUMENTS</b>							
		DOCUMENT NUMBER	DATE	COUNTRY	TRANSLATION		
					YES	NO	
	BD	WO 93/15210	08/05/93	WIPO			
	BE	WO 93/25240 ✓	12/23/93	WIPO			
	BF	PCT/EP90/00565	10/1990	WIPO			
	BG	PCT/GB89/00427	11/02/89	WIPO			
<b>OTHER PRIOR ART</b> <i>(Including Author, Title, Date, Pertinent Pages, Etc.)</i>							
	BH		Curti, "Physical barriers to drug delivery in tumors," <i>Crit. Rev. Oncol. Hematol.</i> 14(1):29-39, February 1993				
	BI		Dermer, <i>Biotechnology</i> 12:320, 1994.				
	BJ	✓	Dischino et al., "Synthesis of Nonionic Gadolinium Chelates Useful as Contrast Agents for Magnetic Resonance Imaging," <i>Inorg. Chem.</i> 30:1265-1269, 1992.				
	BK		Galli et al., "A radiopharmaceutical for the study of the liver: 99MTc-DTPA-ASIAD OROSOMUCOID. II: human dynamic and imaging studies," <i>J. of Nucl. Med. and Allied Sciences</i> 32(2):117-126, 1988.				
	BL		Goodwin et al., "Pharmacokinetics of Biotin-Chelate Conjugates for Pretargeted Avidin-biotin Immunoscintigraphy," <i>J. Nucl. Med. Proceedings of the 39<sup>th</sup> Annual Meeting</i> 33:880, Abstract No. 232, 1992				
	BM		Goodwin et al., "Pretargeted immunoscintigraphy: effect of hapten valency on murine tumor uptake," <i>J. Nucl. Med.</i> 33(11):2006-2013, November 1992.				
	BN		Goodwin, "New methods for localizing infection: a role for avidin-biotin?," <i>J. Nucl. Med.</i> 33(10):1816-1818, October 1992.				
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<b>FOREIGN PATENT DOCUMENTS</b>							
		DOCUMENT NUMBER	DATE	COUNTRY	TRANSLATION		
					YES NO		
	CB						
<b>OTHER PRIOR ART</b> <i>(Including Author, Title, Date, Pertinent Pages, Etc.)</i>							
	CC	Goodwin, "Tumor imaging with indium-labeled biotin," <i>J. Nucl. Med.</i> 32(4):750-751, April 1991.					
	CD	Green, "1. The use of [ <sup>14</sup> C] Biotin for kinetic studies and for assay," <i>Biochem. J.</i> 89:585-590, 1963.					
	CE	Harris et al., "Therapeutic antibodies--the coming of age," <i>TIBTECH</i> 11(2):42-44, February 1993.					
	CF	Hnatowich et al., "Investigations of avidin and biotin for imaging applications," <i>J. Nucl. Med.</i> 28(8):1294-1302, 1987.					
	CG	International Search Report for PCT Patent Application No. PCT/US93/05406.					
	CH	Jain, "Barriers to drug delivery in solid tumors," <i>Scientific American</i> 271(1):58-65, July 1994.					
	CI	Jokiranta et al., "Biotinylation of monoclonal antibodies prevents their ability to activate the classical pathway of complement," <i>J. of Immunology</i> 151(4):2124-2131, August 15, 1993.					
	CJ	Kalofonos et al., "Imaging of tumor patients with Indium-111-labeled biotin and streptavidin-conjugated antibodies: preliminary communication," <i>J. Nucl. Med.</i> 31(11):1791-1796, 1990.					
	CK	✓	Kasprzyk and Wilkins, "Kinetics of Interaction of Metal Ions with Two Tetraaza Tetraacetate Macrocycles," <i>Inorg. Chem.</i> 21:3349-3352, 1982.				
	CL		Koch and Macke, " <sup>99m</sup> Tc Labeled biotin conjugates in a Tumor 'Pretargeting' approach with monoclonal antibodies," <i>Angew. Chem. Intl. Ed. Engl.</i> 31(11):1507-1509, 1992.				
	CM		Kricka et al., "Survey of methods for measuring human anti-mouse antibodies. HAMA Survey Group," <i>Clinica Chimica Acta</i> 215(2):153-163, June 16, 1993.				
	CN	✓	McMurry et al., "Convenient synthesis of bifunctional tetraaza macrocycles," <i>Bioconjugate Chem.</i> 3(2):108-117, 1992.				
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DA							
<b>FOREIGN PATENT DOCUMENTS</b>							
	DOCUMENT NUMBER	DATE	COUNTRY			TRANSLATION YES NO	
DB							
<b>OTHER PRIOR ART</b> <i>(Including Author, Title, Date, Pertinent Pages, Etc.)</i>							
DC	✓	Moi and Meares, "The Peptide Way to Macrocyclic Bifunctional Chelating Agents: Synthesis of 3-(p-Nitrobenzyl)-1,4,7,10-tetraazacyclododecane- <i>N,N',N'',N'''</i> -tetraacetic Acid and Study of Its Yttrium(III) Complex," <i>J. Am. Chem. Soc.</i> 110:6266-6267, 1988.					
DD	✓	Moore, "The Future of Cytokine Combination Therapy," <i>Cancer</i> 67(10):2718-2726, May 15, 1991.					
DE		Osband et al., "Problems in the investigational study and clinical use of cancer immunotherapy," <i>Immunol. Today</i> 11(6):193-195, June 1990.					
DF	✓	Paganelli et al., "Intraperitoneal radio-localization of tumors pre-targeted by biotinylated monoclonal antibodies," <i>Int. J. Cancer</i> 45(6):1184-1189, June 15, 1990.					
DG	✓	Paganelli et al., "Monoclonal antibody pretargeting techniques for tumour localization: the avidin-biotin system. International Workshop on Techniques for Amplification of Tumour Targeting," <i>Nucl. Med. Commun.</i> 12(3):211-234, March 1991.					
DH	✓	Parker et al., "Implementation of macrocycle conjugated antibodies for tumour-targeting," <i>Pure &amp; Appl. Chem.</i> 61(9):1637-1641, 1989.					
DI	✓	Renn and Meares, "Large-scale synthesis of the bifunctional chelating agent 2-(p-nitrobenzyl)-1,4,7,10-tetraazacyclododecane- <i>N,N',N'',N'''</i> -tetra acetic acid, and the determination of its enantiomeric purity by chiral chromatography," <i>Bioconjugate Chem.</i> 3(6):563-569, 1992.					
DJ	✓	Riesen et al., "Synthesis and X-Ray characterization of seven co-ordinate Macrocyclic In <sup>3+</sup> complexes with relevance to radiopharmaceutical applications," <i>J. Chem. Soc., Chem. Commun.</i> 8:460-462, 1989.					
DK		Rosario et al., "Bolton-hunter and biotin derivatization polylysine: a new multi-valent peptide reagent for <i>in-vivo</i> pre-targeting with streptavidin conjugates," <i>J. Nucl. Med. Proceedings of the 38<sup>th</sup> Annual Meeting</i> 32(5):993, Abstract No. 356, May 1991.					
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	EA						
	EB						
	EC						
	ED						
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					YES	NO	
	EE						
	EF						
	EG						
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<i>MFC</i>	EH	Rosebrough, "Plasma Stability and Pharmacokinetics of Radio-labeled Deferoxamine-Biotin Derivatives," <i>J. Nucl. Med. Proceedings of the 39<sup>th</sup> Annual Meeting</i> 33:880, Abstract No. 235, 1992.					
	EI	Sanderson et al., "Preparation and Characterization of Biotin Conjugates of Anti-Pan-Carcinoma NR-LU-10 Monoclonal Antibody for a Three Step Radioimmunotherapy," <i>J. of Nucl. Med. Proceedings of the 39<sup>th</sup> Annual Meeting</i> 33:880, Abstract No. 222, 1992.					
	EJ	✓	Sheldon et al., "Targeting of [ <sup>111</sup> In]biocytin to cultured ovarian adenocarcinoma cells using covalent monoclonal antibody-streptavidin conjugates," <i>Appl. Radiat. Isot.</i> 43(11):1399-1402, November 1992.				
	EK	✓	Sieving et al., "Preparation and characterization of paramagnetic polychelates and their protein conjugates," <i>Bioconjug. Chem.</i> 1(1):65-71, 1990.				
	EL	✓	Virzi et al., "The Preparation and evaluation of 12 biotin derivatives labeled with TC-99M," <i>J. Nucl. Med. Proceedings of the 39<sup>th</sup> Annual Meeting</i> 33:920, Abstract No. 403, 1992.				
	EM	✓	Wolfe et al., "Biotinidase," <i>Methods Enzymol.</i> 184:103-111, 1990.				
	EN	✓	Wu et al., "Investigations of N-linked macrocycles for <sup>111</sup> In and <sup>90</sup> Y labeling of proteins," <i>Int. J. Rad. Appl. Instrum. Part B</i> 19(2):239-244, February 1992.				
	EO		Zwierzina, "Practical aspects of cytokine therapy," <i>Stem Cells</i> 11(3):144-153, May 1993.				
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